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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/080,130  | 02/19/2002  | Romano Deghenghi     | 87264-300           | 9172             |
| 28765   | 7590        | 12/19/2005           | EXAMINER            |                  |
| WINSTON & STRAWN LLP<br>1700 K STREET, N.W.<br>WASHINGTON, DC 20006 |             |                      | VANIK, DAVID L      |                  |
|   |             | ART UNIT             |                     | PAPER NUMBER     |
|   |             | 1615                 |                     |                  |

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                            |                  |
|------------------------------|----------------------------|------------------|
| <b>Office Action Summary</b> | Application No.            | Applicant(s)     |
|                              | 10/080,130                 | DEGHENGHI ET AL. |
|                              | Examiner<br>David L. Vanik | Art Unit<br>1615 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

WHICH EVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) Responsive to communication(s) filed on 06 September 2005.

2a) This action is **FINAL**.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 6,12,13,17-29,32-57 and 59-67 is/are pending in the application.  
4a) Of the above claim(s) 6,18,19,27-29,40,41,43-57 and 59-67 is/are withdrawn from consideration

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 12,13,20-26,32-35,38,39 and 42 is/are rejected.

7)  Claim(s) 36 and 37 is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a))

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892) 4)  Interview Summary (PTO-413)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948) Paper No(s)/Mail Date. \_\_\_\_.  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/16/03; 10/19/05.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_.

**DETAILED ACTION**

Receipt is acknowledged of Applicant's Response to Election/Restriction filed on 9/6/2005. Response is also acknowledged of Applicant's Information Disclosure Statement filed on 10/19/2005.

***Election/Restrictions***

Applicant's election with traverse of Claims 12-13, 18-26, 32-39, 42, 45-52, 55, 59 in the reply filed on 9/6/2005 is acknowledged. Applicant also elected "trifluoroacetic acid" and "Teverelix" as the species. The traversal is on the ground(s) that Groups I-V are unmistakably linked together to provide a single inventive concept – a fluid, milky microcrystalline aqueous suspension. This is not found persuasive because Groups I-V differ in scope as indicated by their distinct classification. Alternatively, Applicant asserts that (1) Groups I, III, V and (2) Groups II and IV should be examined together. Again, as stated above, this is not found persuasive because Groups I-V differ in scope as indicated by their distinct classification. As such, the claims of Groups I-II, IV and V are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and invention, there being no allowable generic or linking claim. As a result of the species election requirements, claims 18-19, 45-52, 55, and 59 are also withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and invention, there being no allowable generic or linking claim.

Newly submitted claims 60-67 are directed to an invention that is independent or distinct from the invention originally claimed. If the dependent claim 12 is found allowable, claims 60-67 will be rejoined. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 60-67 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant timely traversed the restriction (election) requirement in the reply filed on 9/6/2005. The requirement is still deemed proper and is therefore made FINAL.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12-13 and 20-26 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0198146 ('146).

'146 disclose a method for producing peptide salts comprising reacting an acid with a peptide in the presence of diluent in a mixed bed ion exchanger (Claim 1 and

abstract). The result of said method is a stable peptide salt (paragraph 0013 and claims 6-7). Teverelix can be used as a peptide in the invention advanced by '146 and mannitol can be used as the isotonic agent (Claim 2, Example 1, and paragraph 0016). According to '146, the corresponding acid of sulfate, which can be sulfuric acid, can be added to the peptide in order to form a peptide-sulfate salt (paragraph 0017). Like the instant claims 12 and 20-26, the peptide salt is capable of forming a suspension (paragraph 0013 and Example 1). The peptide salt-based composition advanced by '146 can be lyophilized and reconstituted at an amount equal to or higher than 25 mg/ml (paragraphs 0019-0029). Depending on the body weight of the mammal, the amount of the peptide can range from about 0.1 to 5 mg per kg body weight (paragraphs 0019-0029).

Barring a showing of evidence to the contrary, it is also the examiner's position that, inherently, the peptide salt-based composition advanced by '146 is in the form of microcrystals having a particle size between about 1 and 150 nm. Since the essential elements of the '146 composition are identical to the instant compositions (that is, a strong proton donor and a peptide with the same structure as Teverelix wherein said peptide salt is capable of forming a suspension), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '146 anticipates the compositions enumerated in the instant claim set.

Claims 32-35, 38-39, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,258,933 ('933).

'933 disclose peptide salts and methods of making said peptide salts (abstract and Examples 1-7). Like the instant claim 32, '933 disclose Antarelix trifluoroacetate compositions (Example 4). Giving the claims their broadest reasonable interpretation, the examiner is giving no patentable weight to the suspension limitation present in the preamble of the instant claim 32. As such, claim 32 is being interpreted as a Teverelix-trifluoroacetate salt (or Antarelix – same peptide structure). Even though the examiner is not given patentable weight to the “suspension” term present in the preamble, it is still the examiner's position that said Antarelix trifluoroacetate-based composition is inherently in a suspension (Example 4). Additionally, like the instant application, the Antarelix trifluoroacetate-based composition can be freeze-dried or lyophilized (Example 4).

Barring a showing of evidence to the contrary, it is also the examiner's position that, inherently, the Antarelix trifluoroacetate-based composition advanced by '933 is in the form of microcrystals having a particle size between about 1 and 150 nm. Since the essential elements of the '933 composition are identical to the instant compositions (that is, a Antarelix trifluoroacetate-based composition), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '933 anticipates the compositions enumerated in the instant claim set.

Claims 36-37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. WO 00/0047234 ('234) is cited as a patent of interest in its disclosure of a Teverelix-based peptide salt composition (See page 4, line 14; and claim 49).

***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.  
Art Unit 1615



12/11/05

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